K121774

SEP 13 2012

510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
Contact Name and Information	Beth Torok Principal Regulatory Affairs Specialist Phone: 763-494-1273 Fax: 763-494-2222 e-mail: beth.torok@bsci.com		
Date Prepared	15 June 2012		
Proprietary Name	Rotablator™ Rotational Atherectomy System with the Peripheral RotaLink™ Plus		
Common Name	Rotational Angioplasty System		
Product Code	MCW - Catheter, Peripheral, Atherectomy		
Classification	Class II, 21 CFR Part 870.4875 – Intraluminal Artery Stripper		
Predicate Device(s)	Peripheral Rotablator® Rotational Angioplasty System with the RotaLink™ Exchangeable Catheter	K993648	24 November 1999
	Peripheral Rotablator® Rotational Angioplasty System with the Support and Rail RotaWire™ Guidewires	K960379	25 April 1996
	Peripheral Rotablator® Rotational Angioplasty System with Dynaglide	K933238	24 August 1993
	Rotablator wireClip	K913450	06 September 1991
Device Description	The Rotablator Rotational Atherectomy System with the Peripheral RotaLink Plus is a catheter based angioplasty device that utilizes a high speed, rotating, diamond-coated burr to ablate occlusive material and restore luminal patency. The burr spins at up to190,000 RPM and ablates material into very fine particles that are carried distally and removed via the reticuloendothelial system. There are three main components that comprise the Rotablator Rotational Atherectomy: 1) the Peripheral RotaLink Plus, 2) Peripheral RotaWire Guidewire with the wireClip Torquer, and 3) Rotablator Console with Dynaglide foot pedal. Rotaglide, a lubricant is also available as an accessory.		
Intended Use of Device	The Rotablator Rotational Atherectomy System with the Peripheral RotaLink Plus is intended to ablate occlusive material and restore luminal patency in the peripheral vasculature.		
Indications for Use	The Rotablator Rotational Atherectomy System is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.		

Comparison of Technological Characteristics

The Rotablator Rotational Atherectomy System with the Peripheral RotaLink Plus incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices.

Performance Data

Currently no FDA mandated or voluntary performance standards exist for this atherectomy catheter. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility and chemical characterization tests were completed on the Rotablator Rotational Atherectomy System;

Peripheral RotaLink Plus:

Natural Rubber Latex	Intracutaneous Reactivity Test (Irritation)
Hemolysis Assay: Extract Method	Acute Systemic Injection Test
Hemolysis Assay: Direct Contact Method	Materials Mediated Rabbit Pyrogen Test
Complement Activation C3a and SC5b-9 Assay	USP Physicochemical Test for Plastics
Partial Thromboplastin Time (PTT)	In vitro Cytotoxicity Test: MEM Elution
In vitro Hemocompatibility Assay	FTIR Analysis
Guinea Pig Maximization Sensitization Test: Method for Biomaterial Extracts	

Peripheral RotaWire Guidewire:

Natural Rubber Latex	Intracutaneous Reactivity Test (Irritation)
Hemolysis Assay: Direct Contact Method	In vitro Cytotoxicity Test: MEM Elution
Complement Activation C3a and SC5b-9 Assay	Materials Mediated Rabbit Pyrogen Test
Partial Thromboplastin Time (PTT)	USP Physicochemical Test for Plastics
In vitro Hemocompatibility Assay	Acute Systemic Injection Test
Guinea Pig Maximization Sensitization Test: Method for Biomaterial Extracts	

Rotaglide:

Hemolysis Assay: Direct Contact Method	In vitro Cytotoxicity Test: MEM Elution
Partial Thromboplastin Time (PTT)	Materials Mediated Rabbit Pyrogen Test

The following in-vitro performance tests were completed on the Rotablator Rotational Atherectomy System:

Peripheral RotaLink Plus:

Strain Relief	Burr Cutting Ability
Operational Speeds	Tensile Strength
Stall Torque	Brake Engagement
Infusate Temperature Generation	Infusate Flow Rate
Catheter Advancement	Lumen Patency
Component Interface Compatibility	Functional Life

Peripheral RotaWire Guidewire and wireClip Torquer:

Corrosion	Torque Transmission
Radiodetectability	Pushability
Fracture	Tip Deflection
Flexure	Stiffness
Tensile Strength	Torque to Fail
Tip Formability	Functional Life

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Rotablator Rotational Atherectomy System with the Peripheral RotaLink Plus has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Rotablator Rotational Angioplasty System as submitted in K993548, K960379, K933238, and K913450.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Boston Scientific Corp.
% Ms. Beth Torok
One Scimed Place
Maple Grove, MN 55311

Re: K121774
Trade/Device Name: Rotablator Rotational Atherectomy System with the Peripheral RotaLink Plus
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. Torok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121774

Device Name: Rotablator™ Rotational Atherectomy System with the Peripheral RotaLink™ Plus

Indications for Use:

The Rotablator™ Rotational Atherectomy System is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121774